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Calendar No. 690

101ST CONGRESS *2d Session*	SENATE	REPORT 101-369

CONSUMER SEAFOOD SAFETY AND QUALITY ASSURANCE ACT OF 1990

Mr. HOLLINGS, from the Committee on Commerce, Science, and Transportation, submitted the following

REPORT

OF THE

SENATE COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION

ON

S. 2228

JULY 13 (legislative day, JULY 10), 1990.—Ordered to be printed

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Mr. HOLLINGS, from the Committee on Commerce, Science, and Transportation, submitted the following

REPORT

[To accompany S. 2228]

The Committee on Commerce, Science, and Transportation, to which was referred the bill (S. 2228) to develop a comprehensive program to ensure the wholesomeness of fish and fish products intended for human consumption and sold in interstate commerce, and for other purposes, having considered the same, reports favorably thereon with an amendment in the nature of a substitute and recommends that the bill as amended do pass.

PURPOSE OF THE BILL

The purpose of S. 2228 is to establish a comprehensive national program to ensure that fish and fish products intended for human consumption and sold in interstate commerce are safe, wholesome, and accurately labeled.

BACKGROUND AND NEEDS

The amount of seafood eaten in the United States has grown significantly in the last decade. During this period, annual consumption increased by 23 percent, to a record high in 1989 of 15.9 pounds per person. The variety of seafood products also has expanded rapidly, and fish imports now account for roughly two-thirds of the seafood consumed in the United States. In addition, the United States is now the world's largest exporter of fish products, with exports valued at $2,400 million in 1988.

While the health benefits of eating fish have been well documented, concern has grown regarding the adequacy of existing gov-

ernment programs for ensuring that fish is not spoiled or contaminated. Seafood currently is not subject to mandatory continuous inspection. Existing seafood safety programs are a patchwork of State and Federal agency responsibilities. In recent months, consumer advocates and seafood industry leaders have contended that a more aggressive and comprehensive program is needed.

Consumer problems with seafood

Potential hazards from eating seafood fall into three categories: (1) human health threats relating to biological, chemical, or physical contamination; (2) concerns regarding the quality of seafood which may arise from improper handling methods, hygiene, or sanitation that result in a low-quality or unwholesome product; and (3) economic fraud caused by illegal or misleading actions which defraud purchasers, such as species substitution, short weight, and overglazing.

Human health threats.—Cases of illnesses linked to seafood amount to a small percentage of the total number of reported cases of foodborne illnesses. According to data from the Centers for Disease Control (CDC), from 1973 to 1987 shellfish accounted for 2.8 percent of all such cases, and finfish for 2.2 percent of cases, for a combined total of 5 percent.

Though the U.S. seafood consumer is not presently facing a national public health crisis, certain fisheries may warrant stricter regulation to minimize consumer risk. CDC data indicates that, from 1983 to 1987, three hazards accounted for 90 percent of the confirmed seafood health problems: (1) the consumption of raw molluscan shellfish (oysters, clams, and mussles), particularly those harvested, both commercially and recreationally, from polluted waters; (2) scombrotoxic poisoning, which is preventable and affects species such as tuna, mackerel, bonito, and mahi-mahi; and (3) ciguatoxic illness associated with eating tropical reef fishes. Diseases caused by unsafe seafood include botulism, salmonellosis, anasakiasis (round worms), vibrio infections, Norwalk virus, staphylococcal food poisoning, and hepatitis A.

Quality and wholesomeness.—Contamination of seafood often occurs after it reaches the last stage of preparation for human consumption. Improper handling and preparation at home or in restaurants have been cited as reasons for many food-related illnesses. The mishandling factors which are most frequently confirmed include improper refrigeration, improper hotholding, inadequate cooking, unclean equipment, and infected food handlers. Such factors do not necessarily make products unsafe, but quality is reduced and consumers understandably are repelled by any product manufactured or marketed without proper sanitary controls.

Economic fraud.—Economic fraud of consumers may take a number of forms. Because there are many different fish species sold commercially, it is difficult to prevent distributors from substituting one species for another and charging for an expensive product while actually selling a cheaper one. In addition, common names for species may differ from region to region, and ensuring that products are accurately labeled is a challenge. In many cases, mislabeling is not deliberately fraudulent, but a result of insufficient knowledge of the species being sold. Another example of eco-

nomic fraud is the use of excessive amounts of breading or water. In either case, the consumer does not obtain the amount of seafood for which he or she had paid.

Seafood safety programs

The United States stands virtually alone among industrialized fishing nations in that it does not have a systematic, mandatory seafood inspection program, but rather a general compliance program. Food safety programs in the United States are administered at both State and Federal levels. Three alternatives agencies have been proposed to take the Federal lead on seafood safety: the Food and Drug Administration (FDA), the National Oceanic and Atmospheric Administration (NOAA), and the Food Safety and Inspection Service (FSIS) of the Department of Agriculture (USDA). Each of these agencies currently operates some food safety programs. In addition, other agencies such as the Environmental Protection Agency (EPA), CDC, the U.S. Fish and Wildlife Service, and the U.S. Geological Survey gather information and assess factors affecting seafood issues.

Food and Drug Administration.—Under the authority of the Federal Food, Drug, and Cosmetic Act (FFDCA), FDA is responsible for ensuring the safety of all foods destined for interstate commerce. The FFDCA provides for consumer protection against adulterated, decomposed, unsanitary and misbranded products. The FDA budget was $141 million in fiscal year (FY) 1989 and $164 million in FY 1990 for all food safety programs. Currently, the agency spends $23 million annually and employs 300 personnel in seafood programs.

Each year, FDA inspects about 1,200 seafood processing facilities, or about one-fourth of such facilities in the United States. In addition, the agency tests about 1,800 domestic and 4,400 imported seafood samples annually for biological and chemical contamination. A targeted approach is used in the sampling program to address particular FDA compliance concerns such as mercury levels in swordfish or the safety of shrimp imports.

FDA also is the lead agency for two specific programs that regulate seafood—the Canned Salmon Control Plan and the National Shellfish Sanitation Program (NSSP). Finally, FDA operates the low-acid canned food program that includes heat-processed, commercially sterile, canned seafoods.

National Oceanic and Atmospheric Administration.—NOAA was created by the President's Reorganization Plan No. 4 of 1970 to consolidate many of the Nation's civilian oceanic and atmospheric programs. One of the principal roles assigned to the agency at that time was the management of marine resources for the economic and social good of the Nation. Over the years, NOAA has devleoped substantial scientific and technical expertise in managing marine fisheries. Ongoing activities include fisheries research, collection of fishery-related information, enforcement of Federal marine resource regulations, seafood safety and quality assurance programs, and fishery development.

NOAA currently operates seafood safety-related programs at a total cost of about $18 million annually (industry reimbursements provide $6 million to $8 million of this total). Under the authority of the Agricultural Marketing Act of 1946, NOAA carries out vol-

untary seafood inspection and grading programs. The programs are operated on a fee-for-service basis to provide sanitation and processing inspections and product evaluation. Participation by seafood processors allows them to attach "Packed Under Federal Inspection" and "U.S. Grade" marks to their products. The U.S. military forces and a number of foreign and domestic buyers require such an evaluation as a condition of purchase. About 11 percent of the seafood consumed in the United States and 9 percent of our seafood exports are subjected to some inspection under this NOAA program, which involves over 300 Federal and State inspectors.

For the past three years NOAA has been working on the Model Seafood Surveillance Project (MSSP) which is intended to provide the basis for a comprehensive safety and quality assurance program suited to the unique characteristics of the fishing industry. The MSSP is comprised of two parts: first, an assessment of the public health impacts of eating seafood that is now being carried out by the National Academy of Sciences (NAS); and second, the design of a seafood inspection system to minimize potential hazards associated with the handling and processing of seafood. An interim report on the findings of the MSSP was released in March, with completion of the study scheduled for December 1990.

Further, NOAA has conducted the National Shellfish Pollution Indicator Study for the past two years, to develop new techniques for assessing the safety of shellfish growing areas. The current indicators were developed over forty years ago and do not reflect modern advances in food science or microbiology. The absence of a reliable method for determining whether it is safe to eat shellfish from a growing area may be contributing to closure of beds containing harvestable shellfish, while less safe sites are left open.

Food Safety and Inspection Service.—Since 1907, USDA has been authorized to inspect all meat products and, since 1957, all poultry products sold in the United States through interstate commerce. Inspections are carried out by FSIS, which employs more than 9,000 people at an annual cost of over $400 million. USDA currently has no programs addressing seafood safety issues.

State programs.—Most coastal States have seafood safety programs to inspect food establishments, including processors, packers, wholesalers, retail outlets, and restaurants. These State inspection programs are focused primarily on evaluating sanitary conditions. In addition, State officials work cooperatively with FDA and private industry through the Interstate Shellfish Sanitation Conference (ISSC) to implement the NSSP. The purpose of the NSSP is to minimize illnesses associated with eating molluscan shellfish such as oysters, clams, and mussels. The program provides guidelines for State programs whose compliance is evaluated by the FDA. Among the elements of the NSSP are: monitoring and classification of growing waters; enforcement of restrictions on harvesting from polluted growing waters; and inspection of processing plants. States spend an estimated total of $20 million annually on seafood safety programs.

Development of comprehensive program

Development of an effective program to ensure seafood quality and safety is not merely a question of imitating Federal meat and

poultry inspection programs which rely on continuous visual inspection. Unlike meat and poultry, seafood is harvested mainly in the wild, and processing of billions of pounds of fish often occurs in remote locations or onboard fishing vessels at sea.

Directly, or indirectly, the U.S. seafood industry contributes nearly $50 billion to the U.S. economy. The commercial seafood industry is diverse and seasonal, with an estimated 100,000 fishing vessels harvesting over one hundred commercially important species. The processing sector is also varied, and includes many small operations whose equipment and awareness of proper storage and processing techniques vary from rudimentary to sophisticated. Further complicating the situation is the fact that roughly two-thirds of the seafood consumed in the United States is imported from over 120 countries with varying degrees of seafood inspection expertise. Finally, a significant amount of fresh seafood is consumed locally and does not move in interstate commerce, necessitating a strong and continuing involvement at the State level.

Recognition of the unique characteristics of the fishing industry has been translated into a growing consensus that a new approach is necessary for developing an effective seafood safety and quality assurance program. One such approach is the Hazard Analysis Critical Control Point (HACCP) method. HACCP is a systematic approach to food safety, wholesomeness, and prevention of economic fraud. The system consists of: (1) identification and assessment of hazards associated with growing, processing/manufacturing, marketing, preparation, and use of a food product; (2) determination of critical control points to control any identifiable hazard; and (3) establishment of procedures, including sampling and microbiological analysis, to monitor critical control points. Use of a HACCP system for seafood is endorsed by the fishing industry and by government officials. However, it is viewed with some scepticism by consumer groups, because effective implementation of a HACCP system relies heavily on industry cooperation.

The results of a two-year General Accounting Office (GAO) study on seafood inspection issues were released in August 1988. While pinpointing several shortcomings in the current Federal-State inspection system, GAO concluded that seafood does not need a continuous inspection system similar to current Federal meat and poultry inspection. Further, GAO supported NOAA's ongoing MSSP.

A review of the success of major fish-producing countries in capturing and maintaining significant shares of world markets, including their own, reveals several similarities in the manner in which the safety and quality of their seafood are addressed. It has been suggested that, if the United States is to maintain its position as a leading producer of and market for fish and seafood products, our products must meet comparable levels of product safety, quality, and labeling.

LEGISLATIVE HISTORY

The Commerce Committee's jurisdiction over legislation affecting the seafood industry has been recognized consistently for more than 20 years. This jurisdiction has not been limited to legislation

involving fish harvesting, but rather has included all fishery-related activities from vessel construction through processing, transportation, and marketing. In addition, legislation involving the distribution of commodities in interstate commerce, consumer product labeling, consumer education, and scientific research has traditionally been within the jurisdiction of the Commerce Committee. The issue of seafood safety invariably includes consideration of all these elements.

Since the 89th Congress, over 50 bills to require Federal inspection of seafood have been introduced. From the 91st through the 96th Congresses, nine bills calling for seafood inspection programs were referred exclusively to the Commerce Committee. Though the issue has been addressed a number of times in prior years, only once has Congress come close to resolving it. After several months of discussion in the 92nd Congress, the Commerce Committee reported the "Wholesome Fish and Fishery Products Act of 1971." The bill proposed to establish a comprehensive seafood safety program, including a mandatory inspection system. Action on the legislation, however, was never completed. Modern inspection techniques like HACCP were not available at the time, and the difficulty of implementing a continuous visual inspection system was one of the primary reasons that seafood safety legislation was never completed.

Several bills have been introduced in the 101st Congress which would require the Federal Government to take a more aggressive role in ensuring the safety of seafood. S. 2228, the "Consumer Seafood Safety and Quality Assurance Act," was introduced by Senator Hollings on March 1, 1990. The bill is cosponsored by Senators Kerry, Stevens, Mitchell, and Inouye and was referred to the Commerce Committee. Another bill, S. 1245, the "Federal Fish Inspection Act," was introduced by Senator Mitchell on June 22, 1989. S. 1245 was reported by the Agriculture Committee on June 22, 1990, and on June 26, 1990, the bill was referred to the Commerce Committee until close of business July 10, 1990. The principal difference between the bills is in the designation of a lead agency for the program. S. 2228, as introduced, provided the Department of Commerce through NOAA with authority for the program. S. 1245 would name USDA as the lead agency and would result in transfer of $20 million annually from FDA to USDA. The administration has taken a strong position in favor of continuing and strengthening the existing seafood inspection programs operated by FDA and NOAA.

A hearing on S. 2228 was held by the full Committee and the National Ocean Policy Study on May 24, 1990. At that hearing, the administration, State health officials, and representatives of fishing and consumer groups suggested a number of revisions to the legislation. The administration testimony expressed support for a joint program involving FDA and NOAA. The chairman of the ISSC and a consumer representative testified that FDA should retain a lead role in ensuring seafood safety. In addition, several other issues were raised by the witnesses, including funding requirements, the need for close Federal-State cooperation, and the importance of adequately protecting whistleblowers—employees who report unsafe conditions.

The Committee considered an amendment in the nature of a substitute to S. 2228 in open executive session on June 27, 1990. The substitute reflected many of the revisions suggested at the hearing. Responsibility for the program would be handled jointly by FDA and NOAA. In addition, Senator Stevens offered an amendment which was adopted without objection by the Committee. This amendment clarified agency roles in the program; eliminated discretionary authority to include fishing vessels under the program without further legislative action; and broadened the definition of fishing vessel. The Committee then ordered the bill reported favorably, as amended, without objection.

SUMMARY OF MAJOR PROVISIONS

The reported bill calls for the Secretaries of Health and Human Services and Commerce to establish a joint seafood safety and quality assurance program. The purpose of the program would be to ensure public safety and minimize problems associated with eating seafood and to encourage the acceptance of high quality U.S. products in foreign and domestic markets. The Secretary of Health and Human Services (Health Secretary), through FDA, would provide oversight of the program, maintaining the Department's current public health authority. The Secretary of Commerce (Commerce Secretary), through NOAA, would be responsible for routine inspection and industry-related activities.

Principal elements of the program are as follows:

Federal standards

The Health Secretary, in conjunction with the Commerce Secretary, would be required to establish and implement Federal standards in four critical areas: (a) maximum allowable levels of contaminants; (b) procedures for sanitation in seafood processing; (c) product standards for identity, minimum quality and fill of container; and (d) requirements for seafood growing and harvesting areas.

National inspection system

The two Secretaries jointly would develop a system for inspecting seafood to minimize public health hazards and other problems based on the HACCP approach. The frequency of inspection by the Commerce Secretary would be tailored to the seriousness of potential problems associated with each seafood commodity and the processor's history of compliance. Participation and registration of all processing facilities would be required, with an 18-month study to assess inclusion of fishing vessels. Seafood importers would be expected to meet requirements equal to those required for domestic producers. "Whistleblower" protection would be provided for employees who identify potential seafood safety problems or who refuse to carry out actions which would violate the bill.

Monitoring of growing and harvesting areas

The Commerce Secretary, in cooperation with the Health Secretary, would establish a monitoring program to identify the growing

and harvesting locations in which contaminated fish are likely to be caught.

State inspection and monitoring programs

The bill recognizes the essential nature of Federal-State cooperation in implementing an effective national program and provides for technical and financial assistance to States to strengthen their programs. Program authority could be delegated to States that meet national requirements, and grants of up to 60 percent of the cost of operating the program would be provided by the Federal Government.

Public information and consumer education systems

The bill calls for design and implementation of: (a) a public surveillance system through the CDC; and (b) a national education program. Together these program elements would provide for improved collection, analysis, and dissemination of information related to seafood safety problems.

Research

The bill requires development of a comprehensive research plan to address seafood safety questions. In addition, it calls for an intensive research effort to determine the relationship between polluted waters and shellfish contamination.

Authorization of appropriations

The reported bill provides for an initial appropriation of $35 million in FY 1991, which would increase to $90 million over the next three years. These appropriations would cover the expected cost of operating mandatory inspection programs, monitoring of harvesting and growing areas, the Federal share of approved state programs, and research and education costs.

ESTIMATED COSTS

In accordance with paragraph 11(a) of rule XXVI of the Standing Rules of the Senate and section 403 of the Congressional Budget Act of 1974, the Committee provides the following cost estimate, prepared by the Congressional Budget Office:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, July 12, 1990.

Hon. ERNEST F. HOLLINGS,
Chairman, Committee on Commerce, Science, and Transportation, U.S. Senate, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the attached cost estimate for S. 2228, the Consumer Seafood and Quality Assurance Act of 1990.

If you wish further details on this estimate, we will be pleased to provide them.

Sincerely,

ROBERT D. REISCHAUER,
Director.

CONGRESSIONAL BUDGET OFFICE—COST ESTIMATE

1. Bill number: S. 2228.

2. Bill title: Consumer Seafood and Quality Assurance Act of 1990.

3. Bill status: As ordered reported by the Senate Committee on Commerce, Science, and Transportation, June 27, 1990.

4. Bill purpose: S. 2228 would require the National Oceanic and Atmospheric Administration (NOAA) and the Food and Drug Administration (FDA) to establish a seafood safety and quality assurance program. The program would include the establishment of federal standards, a national inspection system, monitoring programs, public education, and research on seafood safety.

5. Estimated cost to the Federal Government:

[By fiscal year,-in millions of dollars]

	1991	1992	1993	1994	1995
Authorization level	35	60	90		
Estimated outlays	26	50	80	20	9

The costs of this bill would be in budget functions 300 and 550.

Basis of estimate: S. 2228 would authorize the appropriation of $35 million in 1991, $60 million in 1992, and $90 million in 1993 for the establishment of a seafood inspection system but would not specify the allocation of these funds between the two agencies. Based on information provided by NOAA and the FDA, we expect that roughly two-thirds of these funds would be for the FDA and one-third would be for NOAA. We also have assumed that the full amounts authorized would be appropriated for each fiscal year. The estimated outlays are based on historical spending patterns.

6. Estimated cost to State and local governments: This bill would authorize grants to state governments with seafood inspection programs that meet national requirements; these grants could cover up to 60 percent of the program costs.

7. Estimate comparison: None.

8. Previous CBO estimate: On June 19, 1990, CBO prepared an estimate for S. 1245, the Fish Safety Act of 1990, as ordered reported by the Senate Committee on Agriculture, Nutrition, and Forestry on May 22, 1990. S. 1245 also would establish a seafood inspection program, but would place most of the program responsibilities under the Secretary of Agriculture. In total, CBO estimates that S. 1245 would authorize appropriations of $15 million for 1991, $41 million for 1992, and $81 million for each of fiscal years 1993 through 1995; these figures include a savings of roughly $20 million per year in fiscal years 1994 and 1995 from the FDA relinquishing its inspection activities.

9. Estimate prepared by: Michael Sieverts and Karen Graham.

10. Estimate approved by: James L. Blum, Assistant Director for Budget Analysis.

REGULATORY IMPACT STATEMENT

In accordance with paragraph 11(b) of rule XXVI of the Standing Rules of the Senate, the Committee provides the following evaluation of the regulatory impact of the legislation, as reported.

Number and type of persons regulated

Registration, inspection, and reporting requirements under sections 6 and 7 of this bill would apply to all seafood processing facilities and commercial importers. In addition, sanitation standards may be established for harvesting vessels, although such vessels would be exempted from the registration and inspection requirements of sections 6 and 7.

Economic impact

The Departments of Health and Human Services and Commerce will incur some costs in fulfilling Federal responsibilities required under this legislation. The funding necessary to carry out these responsibilities should be modest and is not expected to have an inflationary impact on the Nation's economy. A portion of these costs may be incurred in the administration of voluntary grading programs, in providing export exemptions and certificates, and in increased inspection of imports from nations without adequate seafood safety programs. That portion may be recovered through the charging of fees to processors and importers requesting such additional services. A modest sum of money is also authorized for funding seafood safety research, for improving public health surveillance efforts, and for consumer education.

One of the goals of the new program is to promote commerce in seafood by encouraging the acceptance of wholesome U.S. products in foreign and domestic products. As this goal is realized, the U.S. economy and the seafood industry in particular should accrue substantial economic benefits.

Privacy

This legislation will not have any adverse impact on the personal privacy of the individuals involved.

Paperwork

Some additional paperwork will be required from the commercial seafood industry in order to comply with the registration and reporting provisions of this legislation. Similar paperwork is already required for some existing fisheries programs, and the bill requires the Health and Commerce Secretaries to coordinate and integrate their regulatory activities, which should minimize new paperwork requirements.

Some new paperwork also will be required of the Health and Commerce Secretaries. The Health Secretary would prepare an annual report regarding the progress in developing contaminant standards. Timely reports to Congress also would be submitted regarding significant findings of the surveillance system established through the CDC. In addition, the Commerce Secretary would submit to Congress an annual written report on the administration of the import program, a biennial report on the research program

authorized in section 17, and the results of the study on fishing vessels exempted from the program.

SECTION-BY-SECTION ANALYSIS

Section 1.—Short title and table of contents

This section cites the short title of the bill, the "Consumer Seafood Safety and Quality Assurance Act of 1990," and provides a table of contents.

Section 2.—Findings and purposes

This section provides the findings and purpose of the legislation. Subsection (a) contains findings describing the rationale for establishment of a comprehensive national seafood safety and quality assurance program. They emphasize the importance of seafood to the Nation's food supply, increased consumer awareness of the health benefits associated with eating seafood, and the size and diversity of the commercial fishing industry. The findings also recognize that the sale of unsafe and misbranded fish products results in injury to consumers and losses to the U.S. seafood industry. Finally, the subsection states that existing programs are outdated and inadequate for ensuring consumer confidence and that a comprehensive program is needed.

Subsection (b) of this section outlines three purposes of the legislation: (1) to safeguard the safety of fish and fish products sold in interstate commerce to consumers; (2) to increase the health benefits of consuming seafood and enhance public confidence; and (3) to promote seafood trade by encouraging the acceptance of wholesome products in foreign and domestic markets.

Section 3.—Definitions

This section provides detailed definitions of the terms used in the bill. Several of the definitions, including those for "adulterated," "label," "labeling," and "misbranded," are derived from the FFDCA. In addition, such essential terms as "contaminant," "fish product," "process," and "processing facility" also are defined. The definitions of the terms "adulterated" and "contaminant" employ the phrase "may render the fish or fish product injurious to health." In developing standards and regulations to implement the legislation, the Committee intends that the interpretation of this phrase will be made in light of the administrative and judicial interpretations and precedents under the FFDCA. The term "processing facility" includes both processing vessels and on-shore establishments.

Section 4.—Seafood Safety and Quality Assurance Program

This section establishes a comprehensive seafood safety and quality assurance program. Subsection (a) of this section requires the Health Secretary, in cooperation with the Commerce Secretary, to establish the program within two years of the date of enactment. The Secretaries of Agriculture and Transportation would be consulted in developing the new program, as well as the Chairman of the ISSC, the heads of other appropriate agencies, and representatives of the seafood industry and national consumer organizations.

To the extent practicable, the Committee expects that the new program will build upon and incorporate existing government activities and expertise.

Subsection (b) of this section lists program requirements which would result in the implementation of a HACCP system of inspection. These requirements include: (1) the recognition of the unique characteristics of seafood and the fishing industry; (2) health-based standards for safety and sanitation in harvesting and processing seafood; (3) a comprehensive evaluation of the processing and distribution of seafood to identify potential health risks, determine sources of potential contamination and assess the potential for the persistence or multiplication or concentration of contaminants; (4) procedures to prevent, eliminate, or control potential contaminants and to monitor those procedures; (5) the implementation of a system to monitor fish growing and harvesting areas; (6) authority and compensation to State governments for conducting inspection, enforcement and monitoring activities; (7) design and implementation of national consumer information and education programs; and (8) establishment and administration of a shellfish indicator research program, as well as other research under the bill.

Finally, subsection (c) of this section requires that the program established in subsection (a) be consistent, to the maximum extent practicable, with the NSSP.

Section 5.—Federal seafood standards

This section requires the establishment of Federal seafood standards and the promulgation of regulations and guidelines to apply and enforce such standards. Subsection (a) of this section requires that standards be developed and implemented in four areas: contaminant levels; sanitation and quality control; product identity and composition, minimum quality, and fill of container; and fish growing and harvesting areas.

Subsection (a)(1) requires the Health Secretary to develop and prescribe standards for maximum contaminant levels, including use of indicator organisms, for seafood products intended for human consumption. Since seafood is just one component of a varied diet, the Committee expects standards for seafood contaminants to be developed using methodologies no stricter than those used for other food standards as provided in the FFDCA. In addition, the Committee anticipates that the Health Secretary will examine existing Federal regulations and standards for food products that are applicable to seafood to ensure that the standards and regulations developed under the bill are consistent with such existing standards. The Health Secretary is encouraged to consult with other agencies, the seafood industry, and consumer groups during the standard development process. Finally, the bill is not intended to change the existing authority of the EPA to set tolerances for pesticides under the FFDCA.

Subsection (a)(2) calls on the Health Secretary, in cooperation with the Commerce Secretary, to develop health-based and other appropriate standards of sanitation and quality control for seafood processing. These standards must be based on the evaluation required by section 4(b)(3) and take into account the results of the MSSP of the National Marine Fisheries Service. In addition, the

standards would include all applicable sanitation practices established by the Health Secretary, the Commerce Secretary, and the NSSP. Finally, the Health Secretary could not require the freezing or cooking of seafood intended for raw consumption unless the Health Secretary determines that such freezing or cooking is the only practical procedure available which will prevent adulteration of a specified fish species. Species which pose no hazard should not be treated in the same manner as fish species which do create problems when eaten raw or after little cooking.

Subsection (a)(3) requires the Health Secretary to prescribe standards of identity and composition, minimum quality, and fill of container for seafood. These standards should build on existing Federal regulations and include consideration of any applicable international standards related to seafood. The Committee intends that the Secretary will consult with industry and consumers in all regions of the country in developing standards to accommodate variations that occur in a large and diverse seafood industry. Further, the Commerce Secretary is authorized to establish voluntary grading criteria for seafood which exceed minimum quality standards developed under this subsection.

Subsection (a)(4) would require the Commerce Secretary, in cooperation with the Health Secretary and in consultation with the Administrator of EPA and the Chairman of the ISSC, to prescribe standards for fish growing and harvesting areas in subsection (a)(4). In developing these standards, a comprehensive assessment is required of the effectiveness of existing Federal standards and guidelines for classifying shellfish growing areas. The purpose of the standards is to improve the effectiveness of efforts to identify and control harvesting from areas in which the fish are likely to contain contaminant levels which exceed the standards established under the bill.

Subsection (b) of this section requires the Health Secretary and the Commerce Secretary to promulgate regulations establishing the standards described in this section. While no timetable for the regulations is provided, the Committee anticipates that such standards will be developed and put in place during the two-year period after the date of enactment and before the national program is initiated. The subsection also provides for review of the standards, regulations, and guidelines and revision as necessary to reflect changes in processing methods and related advances in science and technology. Further, in developing the contaminant standards, the Health Secretary, within 30 days after the date of enactment, would contract with the NAS to identify the contaminants likely to be found in seafood and recommend priorities for the development of standards for contaminant levels. The Health Secretary then would use those recommendations in establishing standards for contaminants, placing highest priority on those which represent the greatest public health concern.

Subsection (c) of section 5 requires the Health Secretary to report annually to Congress regarding progress in establishing contaminant standards. This annual report would: (1) describe the research results and priorities; (2) specify the public health significance of any failure to have established standards; (3) specify a timetable

for the development of additional standards; and (4) estimate the costs associated with the development of such standards.

Section 6.—Registration of processing facilities and importers

This section outlines procedures for registering all processing facilities and importers. Subsection (a) calls on the Commerce Secretary, in consultation with the Health Secretary, to establish procedures for registering processing facilities and businesses engaged in the commercial importation of seafood. No processing facility or importer would be authorized to process or handle fish and fish products unless registered by the Commerce Secretary.

Subsection (b) of this section provides registration guidelines for applicants. Each application would require the name of the owner and operator of the processing facility or import business, the principal place of business, and a list of each type of seafood processed or imported. Upon receipt of a completed application, the Commerce Secretary would issue a certificate of registration to the applicant or notify promptly the applicant in writing of the reasons for denial. Any applicant denied a certificate of registration would be provided an opportunity for a hearing upon request.

Subsection (c) authorizes the Commerce Secretary, in consultation with the Health Secretary, to invoke sanctions if a processing facility or importer registered under this section is not in compliance with the requirements or regulations of the bill. After providing a notice of noncompliance and an opportunity for a hearing, the Commerce Secretary could revoke the registration, suspend the registration for a period of time, or impose conditions and restrictions on the registration. The Commerce Secretary may suspend the registration of a processor or importer prior to providing notice and an opportunity for a hearing for failure to permit access for inspection. The Committee intends that any such suspension would be temporary and that prompt notice and opportunity for a hearing would be provided.

Subsection (d) outlines procedures for reinstatement of a registration that has been revoked or suspended. A registration would be reinstated upon a determination that the holder of the registration is fit to engage in fish processing. In addition, the Commerce Secretary would remove conditions or restrictions placed on a registration if the holder of the registration was found to have taken adequate measures to come into compliance with the bill.

Subsection (e) requires registrants to maintain records and provide such information as the Health Secretary, in consultation with the Commerce Secretary, may establish by regulation. Recordkeeping requirements placed on processing facilities under this section would be limited to information necessary for assessing whether the products and operations of a facility were in compliance with the regulations and standards of the bill. Each registrant would be required to permit the Commerce Secretary to have access to and copy these records upon request and at reasonable times.

Subsection (f) requires the Commerce Secretary to assign each registrant a unique identification code.

Section 7.—Federal inspection system

This section requires the Health Secretary to establish and implement, in cooperation with the Commerce Secretary, a comprehensive seafood inspection system. In subsection (a), general oversight authority is provided to the Health Secretary, while routine inspections would be carried out by the Commerce Secretary. Elements of the inspection system would include: random, unannounced inspections of processing facilities; training of inspectors and processing personnel; sampling of products for contaminants; and requirements for recordkeeping, marking, and labeling. Inspection frequency would be determined by a number of factors, including the type of operation, the facility's history of compliance, and the potential for public health problems. The Committee intends that the inspection system developed under this section will result in processors and importers having inspectors from only one agency—the Department of Commerce—visiting their facilities on a regular basis. Any inspection required by the Health Secretary for oversight purposes should be done in the company of the regular inspecting agent.

Subsection (b) authorizes inspection officers to enter facilities, carry out inspections, sample products, and detain and condemn those products which are found to be adulterated or misbranded.

Subsection (c) of this section provides for the segregation, impoundment, and condemnation of all fish and fish products found to be adulterated or misbranded. If an owner objects within 48 hours, products that are perishable would be processed to the extent necessary to prevent spoilage, pending a hearing or judicial review. If inspection officials determine that, after relabeling or other action, the product has been brought into compliance with the Act, entry of the product into interstate commerce would be permitted. Condemned fish or fish products would be destroyed for human food purposes.

Subsection (d) requires each package of seafood that is processed by a registered processing facility to be marked with the unique code assigned that facility and a label bearing the official mark at the time the package leaves the processing facility. The Commerce Secretary would be authorized to exempt a processing facility from this requirement if the facility is not the primary processor and the exemption would not create enforcement or safety problems.

Subsection (e) requires that the inspection officer, before leaving the processing facility, give the owner or operator of the facility a report in writing describing the results of the inspection.

Finally, subsection (f) would authorize the Health Secretary or the Commerce Secretary, as appropriate, to apply for trademark protection for an official mark or device required in implementing the bill.

Section 8.—Monitoring growing and harvesting areas

Section 8(a) requires the Commerce Secretary, in cooperation with the Health Secretary and the Chairman of the ISSC, to establish and maintain a comprehensive system for monitoring and classifying fish growing and harvesting areas. The purpose of the

system is to identify problem areas from which contaminated fish are likely to be harvested.

Subsection (b) of this section authorizes the Commerce Secretary to designate an area monitored under this section as a restricted harvesting area if the Secretary determines that fish harvested from that area are unlikely to meet Federal standards. An area under State jurisdiction from which shellfish are harvested would be treated as a restricted harvesting area if: (1) the State does not have a system in effect for the area in question that is at least equal to the system established under this section; or (2) the State has prohibited the harvesting of shellfish from the area.

Subsection (c) requires the Commerce Secretary to review restricted harvesting areas periodically and to withdraw or modify the designation if it is no longer warranted. Such a review also would be required if requested by the Governor of an affected State or upon petition by affected fishermen, if the petition is accompanied by information indicating that the designation is no longer necessary.

Subsection (d) of this section stipulates that the Commerce Secretary must provide public notice and inform the Health Secretary, the Governor of an affected State, the Chairman of the ISSC, and the Chairman of an affected Regional Fishery Management Council before taking action under this section.

Section 9.—Recall

This section provides authority to the Health Secretary to require any person who owns or operates a processing facility or imports fish and fish products to recall any product if there is a reasonable probability that such product could cause a serious, adverse health consequence or death. The Health Secretary, in consultation with the Commerce Secretary, must promulgate regulations for tracing fish and fish products in connection with a recall ordered under this section.

Section 10.—Imports

This section establishes criteria for ensuring that seafood imports are held to the same standards as domestic products. Under subsection (a), seafood imports must: (1) not be adulterated or misbranded: (2) comply with all standards applicable to seafood in interstate commerce; (3) be marked and labeled as required by regulations; and (4) comply with the requirements of this section. Imports which meet the criteria would be treated as domestic products.

Under subsections (b) and (c), random inspection and sampling of seafood imports would be mandatory, and all products that are refused entry because they do not meet the import criteria would be destroyed unless exported within a designated time or brought into compliance with the Act.

Subsection (d) specifies that storage, cartage, labor, and other costs resulting from the denial of entry are solely the responsibility of the owner or consignee. Failure to pay such costs would constitute a lien against that seafood or any future imports by the owner.

Subsection (e) would authorize the Commerce Secretary, in cooperation with the Health Secretary and through the Secretary of

State, to enter into an agreement with any nation wishing to export seafood to the United States. Such an agreement would be required to: (1) include an evaluation of the adequacy of the nation's seafood safety and quality assurance program; and (2) ensure reciprocity between the two nations with respect to trade in seafood. The Health Secretary would, upon entry into force of such an agreement, issue a certificate to those nations which maintain a program at least equal to that of the United States. The certificates would be subject to review at five-year intervals. All imports from any nation which does not enter into an agreement or have a certificate would be subject to inspection.

Finally, subsection (f) of this section requires the Commerce Secretary, in cooperation with the Health Secretary, to report to Congress annually on the status of foreign seafood inspection programs and the level of imports.

Section 11.—Exports

This section allows an exemption from specific requirements of the bill for seafood products intended for export to a foreign nation. Under subsection (a), a product may be exempted if it is necessary to avoid conflict with a law or custom of the importing nation. Such an exempted product wuld be deemed not to be adulterated or misbranded if certain conditions specified in this section are satisfied.

Subsection (b) instructs the Commerce Secretary to inspect seafood products intended to be exported to foreign nations in the manner and frequency determined by the Health Secretary to ensure compliance with the bill.

Subsection (c) requires the Commerce Secretary, upon request, to provide a certificate of export stating the condition of the fish or fish product inspected.

Section 12.—Prohibited acts and penalties

Section 12(a) outlines a number of actions which would be prohibited under the Act. The prohibited acts include: (1) processing, selling or importing adulterated or misbranded fish or fish products; (2) processing of seafood in a manner that is not in compliance with the Act; (3) transporting in interstate commerce seafood that is adulterated, misbranded, or not processed in compliance with the Act; (4) committing any action that results in the adulteration or misbranding of seafood involved in interstate commerce; (5) falsely representing, forging, or counterfeiting, or without authorization, defacing, altering, or detaching, an official mark or registration; (6) refusing to permit entry to or inspection of a processing facility by an authorized person; and (7) creating or maintaining false records.

Subsection (b) sets civil penalties at $5,000 per violation. Each day of a continuing violation would constitute a separate offense.

Subsection (c) sets criminal penalties at $10,000 or imprisonment for not more than one year, or both. However, if the violation involves intent to defraud or distribution of adulterated fish and fish products, the fine is set at $20,000 or imprisonment for not more than three years, or both.

Subsection (d) provides for issuance of a notice of warning for cases of one or more minor violations.

Finally, subsection (e) provides an exemption from penalties for a common or contract carrier, insofar as the carrier, at the time of receipt, carriage, holding, or delivery, had no reasonable cause to believe there was a violation and if the carrier is willing to provide the name and address of the person from whom the carrier received the fish or fish products in question, as well as documents associated with the delivery.

Section 13.—Hearings and subpoenas

Section 13(a) states that the Health Secretary or the Commerce Secretary shall provide any person adversely affected by actions taken under this Act with an opportunity for a hearing. Subsection (b) of this section authorizes the appropriate Secretary to issue subpoenas requiring witnesses to testify or produce documentation or other evidence that relates to any matter under investigation or in dispute.

Section 14.—Whistleblower protection

This section provides for protection of workers who present evidence that an employer is in violation of the bill. The provision is patterned after language contained in the Surface Transportation Assistance Act of 1982 (49 APP. U.S.C. 2305).

Subsection (a) prevents an employee from being discharged, disciplined, or discriminated against by an employer for filing a complaint or initiating a proceeding relating to a violation of the bill. This protection also is extended to an employee who serves as a witness in any proceeding.

Subsection (b) provides protection for workers who refuse to perform their duties if performing those duties would result in a violation of the bill. In order to qualify for protection under this subsection, the employee must have sought from the employer, and have been unable to obtain, correction of circumstances which would lead a reasonable person to refuse to perform such duties out of a genuine belief that serious injury to the public would result.

Subsection (c) provides procedures for filing complaints under this section. The Secretary of Labor (Labor Secretary) would receive employee complaints concerning actions by the employer to discipline, discharge or discriminate against an employee in violation of this section. The Labor Secretary would assess the validity of such complaints, and take action to abate the violation and compensate the complainant if the employee's actions are determined to have been justified. Detailed time schedules are provided for each step of the process.

Subsection (d) of this section provides for judicial review of actions taken pursuant to subsection (c). The petition for review must be filed within 60 days from the issuance of the Labor Secretary's order.

Subsection (e) would require that the Labor Secretary file a civil action in U.S. district court against any person who fails to comply with a preliminary order issued under subsection (c). If actions are brought under this subsection, the district courts have jurisdiction to grant all appropriate relief.

Section 15.—Surveillance by Centers for Disease Control

This section provides for establishment of an active surveillance system through the CDC. Subsection (a) of this section requires the surveillance system to be based on a representative sample of the population of the United States. The system would assess the frequency and source of human health problems in the United States associated with seafood consumption.

Subsection (b) specifies factors to be considered in assessing seafood-related health problems: (1) an analysis of hazards associated with commercial harvesting and processing as compared with recreational or subsistence harvesting and noncommercial preparation; (2) a comparison of domestic and imported seafood in terms of their respective hazards; and (3) an analysis of consumer-related health problems.

Subsection (c) would require the Health Secretary to make timely reports to Congress on any significant findings.

Section 16.—Consumer education

This section would require the Health and Commerce Secretaries to establish a national consumer education program to provide consumers, processors, and fishermen with information regarding Federal seafood standards and good seafood handling and processing procedures, as well as advice to individuals involved in recreational and subsistence fisheries concerning health hazards associated with fish they may harvest.

Section 17.—Research priorities

Section 17(a) would require the Commerce Secretary, in cooperation with the Health Secretary, to establish and administer a five-year grant program for shellfish indicator research. The grant program would: (1) develop a classification system for shellfish growing waters based on the latest microbiological and epidemiological methods; (2) evaluate representative estuaries in each of the major shellfish growing regions of the United States; and (3) provide recommendations pertaining to shellfish management for each region. Establishment of an advisory panel is authorized to assist in the development and implementation of the research program. Finally, biennial reports to Congress are required regarding significant research results and the progress of the program.

Subsection (b) of this section would require the Health and Commerce Secretaries jointly to develop and publish in the Federal Register a strategic plan for research on fish and fish product safety. The strategic plan would take into consideration the requirements of the Act and establish priorities for a comprehensive research program.

Section 18.—Regulations

This section states that the Health and Commerce Secretaries each may promulgate regulations necessary to carry out the bill. The Secretaries are required to ensure that all regulations are developed and implemented consistently.

Section 19.—State and interagency cooperation

This section provides procedures for establishing State seafood safety programs and delegating authority to the States to implement the Federal program. Subsection (a) of this section states that the Health and Commerce Secretaries must encourage States to continue, strengthen, or establish seafood safety and quality assurance programs at least equal to the program established under the bill.

Subsection (b) authorizes the Health Secretary, in consultation with the Commerce Secretary, to provide States with advisory and technical assistance and financial support for development of state seafood safety programs.

Subsection (c) would allow the Governor of any State to apply to the Health Secretary for approval to administer its own federally-equivalent seafood safety and quality assurance program. Unless the Health Secretary in consultation with the Commerce Secretary determines that the State program lacks adequate authority and capacity to satisfy the four prerequisites stated in subsection (c), the Health Secretary shall approve the program and designate the State as one in which the Federal program does not apply for a period of up to five years. Each State with an approved program becomes eligible to receive an annual grant for up to 60 percent of the cost of operating the program. The Health Secretary, in cooperation with the Commerce Secretary and the Chairman of the ISSC, is required to monitor approved State programs to ensure that they maintain necessary program standards. Federal assistance may be withheld if the State program fails to meet the requirements of the bill.

Finally, subsection (d) of this section would authorize the Health Secretary or the Commerce Secretary, as appropriate, to enter into service agreements with Federal, State, or local agencies or foreign governments on a reimbursable basis for the use of the personnel, services, and facilities of such agencies in conducting registration, inspection, monitoring, and certification under the bill. Information collected by States, local agencies, or foreign governments under this section would be made available to the public in accordance with the requirements of section 552 of title 5, U.S. Code (Freedom of Information Act).

Section 20.—Recovery of costs

Section 20(a) authorizes the Health and Commerce Secretaries to develop a system of user fees for: (1) inspection services to certify voluntary grading standards which exceed minimum quality standards; (2) provision of certificates of export; and (3) inspection of imports from nations which have not entered into a bilateral agreement with the United States.

Subsection (b) stipulates that any fees, late payment penalties, or interest earned from fees collected will be credited to a trust fund account and will remain available without fiscal year limitation to pay the expenses of the Health and Commerce Secretaries, as appropriate, incident to providing these services.

Section 21.—Exemptions and exclusions

Section 21(a) provides exclusions from the bill. The provisions of the bill do not apply to: (1) seafood processing for subsistence purposes; (2) producers of industrial products that are not intended for human consumption; and (3) restaurants, retail stores and recreational vessels.

Subsection (b) exempts from sections 6 and 7 those fishing vessels that harvest or commercially prepare fish and fish products by gutting, decapitating, gilling, icing, freezing, or brine chilling. The Committee intends to exclude all vessels that harvest fish or fish products and undertake the listed preparations for the sole purpose of allowing transport of the fish or fish products to a processing facility for processing and packaging. The Committee does not intend this exemption to apply to fishing vessels that decapitate, gut, freeze, and box fish for shipment to market.

Subsection (c) excludes contract or common carriers that transport seafood already processed, except as provided in section 12 of the bill.

Subsection (d) instructs the Commerce Secretary, in consultation with the Health Secretary, to carry out an 18-month study of the role of exempted vessels in producing seafood and to assess the need for including any particular type of class of fishing vessels under the registration or inspection requirements of the bill.

Section 22.—Authorization of appropriations

This section authorizes annual appropriations of $35 million for FY 1991, $60 million for FY 1992, and $90 million for FY 1993.

Subsection (b) provides for $15 million of that annual appropriation to be used in funding the research program established under section 17 of the bill.

AGENCY COMMENTS

THE WHITE HOUSE,
Washington, DC.

Hon. ERNEST F. HOLLINGS,
Chairman, Committee on Commerce, Science, and Transportation, U.S. Senate, Washington, DC.

DEAR SENATOR HOLLINGS: The status of the federal seafood safety program has been the subject of considerable debate in Congress during recent months. There has been some confusion regarding the Administration's views, and I am writing to clarify our position.

The Administration believes that overall responsibility for seafood safety should remain with the Food and Drug Administration (FDA) of the Department of Health and Human Services and the National Marine Fisheries Service (NMFS) of the Department of Commerce. The expansion of the federal seafood safety program in the President's FY 1991 budget is, therefore, directed toward those agencies. Furthermore, the Administration supports user fees for those services that impart substantial private benefit to the seafood industry. The seafood industry has requested additional federal inspection, which would increase public confidence and enhance sea-

food marketing opportunities. For these reasons, the Administration supports user fees to finance an expanded program.

FDA's seafood safety program currently includes mandatory, random inspections and extensive research, and relies on long-standing relationships with states, other federal agencies and foreign countries. Many of the activities in FDA's program require highly specialized knowledge and training, including expertise in marine biology and related marine disciplines. FDA's program should remain the cornerstone of the federal regulatory system for seafood.

NMFS is the only federal agency authorized to control fishing activities of vessels in federal waters and has closed those waters to harvesting when a FDA tolerance for a contaminant in shellfish has been exceeded. NMFS has an unsurpassed knowledge of fishing vessels and acceptability of catch. Like FDA, NMFS has experience in inspecting seafood processors under its current voluntary program. This program includes grading and lot certification for export, features important for international trade. NMFS is also the lead federal agency with respect to fisheries trade policy and strategy.

The clearest health risk from seafood involves the consumption of raw molluscan shellfish, although less than one percent of all seafood is consumed that way. This risk stems largely from human pollution of coastal waters. Monitoring the quality of local growing waters is the only viable recourse. FDA and NMFS, working with the states, are uniquely qualified to address this public health problem. All state shellfish safety programs for monitoring growing waters are bases on FDA training and rely on FDA technical assistance. An enhancement of this program is best implemented by FDA and NMFS.

The Administration has proposed a $14 million increase in FDA's 1991 budget to accommodate an enhanced program. We believe that the public health interests of the Nation would best be served by a modest but well-targeted expansion of the programs operated by FDA and NMFS.

We look forward to working with you as you continue to examine this issue.

Sincerely,

JOHN H. SUNUNU,
Chief of Staff.

CHANGES IN EXISTING LAW

In compliance with paragraph 12 of rule XXVI of the Standing Rules of the Senate, the Committee states that the bill as reported would make no change to existing law.

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